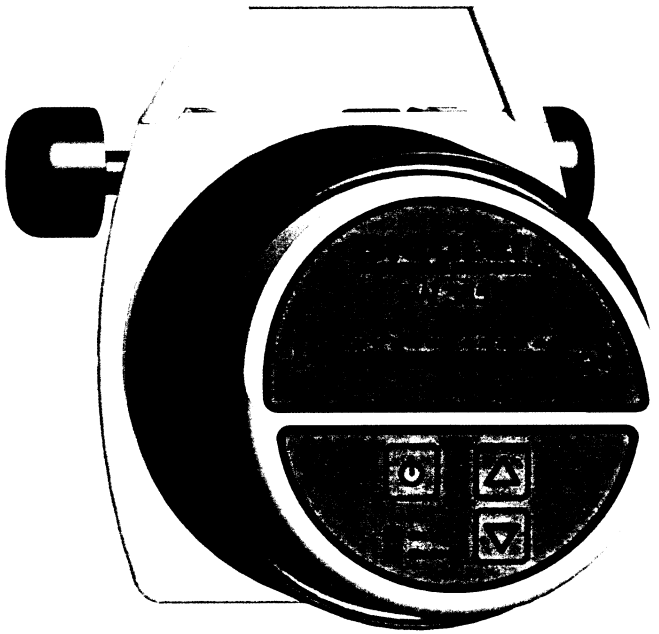
Instructions for use

BW 585
Blood and Infusion Warmer



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EN - Edition 03 / 2007

BIEGLER
MEDIZINELEKTRONIK

IMPORTANT:

These instructions are an essential part of the device. They must therefore be kept in a suitable place near the device and should accompany the device if it is transferred to other users.

For proper and safe use of this device it is essential that the warnings and safety instructions, as well as the instructions for use are read and carefully observed by all users before first using the device.

It is the responsibility of those using the device to fully acquaint themselves with its proper use and operation.

If a malfunction is suspected, the device is to be taken out of service immediately and suitable warning signs should be attached to the device to ensure that it cannot be used before necessary service and repair work has been carried out.

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1 WARNINGS AND SAFETY INSTRUCTIONS

- In the event of any suspected malfunction while in operation, the device should be immediately removed from service and not used for infusions or transfusions until appropriate investigations have demonstrated that there has been no impairment.
- If the high temperatur alarm is triggered the supply of liquid to the patient must be immediately stopped by disconnecting the connection tube to the patient. The medium being used in the device must no longer be administered to the patient.
- Non-compliance with the flow direction specified in the instruction manual may lead to a deviation in the selected control temperature. This could result in damage to the medium.
- The device may only be fastened to infusion stands or tripods which are suitable due to their stability and load capacity.
- Only sterile BIEGLER consumable materials may be used in conjunction with the BW 585.
- The device must only be used in areas in which the electrical installations are in accordance with the rules and regulations in force.
- Safe disconnection from the mains power supply can only be achieved by unplugging the mains plug.
- The device must not be used in rooms subject to explosion hazard.
- Repairs and modifications to the device may only be carried out by persons or service centres authorized by BIEGLER.
- The device must not be immersed in liquids or sterilized with steam or by thermochemical methods.
- All extraneous influences such as radiation or high temperatures are to be kept to a minimum.
- Avoid exerting force to the device or its accessories.
- If the device is dropped, damaged by force or if it shows a function deviating from the instructions for use, do not use the device and return it to the service centre.
- The periodic technical safety inspections must be carried out according to the section „periodic inspections“.

The BW 585 must not be used in the following circumstances:

- If the case is damaged or one of the front film layers becomes detached
- If the device has been exposed to a hard physical shock (e.g. dropped, hit or shaken)
- If the device has been immersed in water
- If the device has triggered a high temperatur alarm that was not caused by external factors
- If the mains power cord or plug is damaged
- If the device has given somebody an electric shock
- If the fixing clamps are damaged and no longer assure safe clamping to the infusion stand

Should a malfunction be evident, suitable warning signs should be attached to the device to ensure that it cannot be used before necessary service and repair work has been carried out.

2 DESCRIPTION

2.1 GENERAL DESCRIPTION

The BIEGLER BW 585 is a warmer for infusions or transfusions and operates on the basis of continuous flow heating, where the heat from the heat exchanger is transferred via the extension tubing to the liquid flowing within it.

The patented groove design enables several extension tubes to be used, provided that there is sufficient heating provided for each of the tubes placed in position.

The design of the casing allows rapid and simple fitting to any suitable infusion stand. The temperature of the heating element can be set between 37°C and 41°C in steps of 0.5°C and is displayed as an illuminated band.

The preset temperature after switching on the BW 585 is 38.5°C.

The alarm and self-test functions for high and low temperature that are incorporated into the device assure safe operation.

2.2 SCOPE OF DELIVERY

Blood and infusion warmer BW 585 and instructions for use.

2.3 CONSUMABLE MATERIAL

Various consumable materials are available according to requirements.

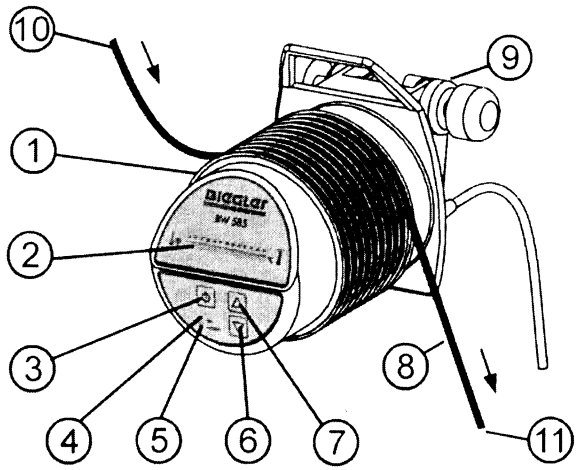
Order numbers:

Extension set	3.5 m	FP1002001	Order no. 35000
Extension set	4.6 m	FP1760110	Order no. 45000
Extension set with bubble trap	4.6 m	FP4600001	Order no. 25000

3 INITIAL OPERATION

Users must familiarise themselves in detail with the contents of these instructions for use before putting the system into operation.

3.1 SETTING UP PROCEDURE



Diag. 1

1 Heat exchanger
2 Temperature scale
3 ON / STANDBY switch
4 LED indicator ON
5 LED indicator STANDBY
6 Control to decrease temperature
7 Control to increase temperature
8 Extension tube
9 Clamps
10 Entry of liquid
11 Exit of liquid
→ Flow direction

Fix the BIEGLER BW 585 firmly to the infusion stand using the clamps at the back (Diag.1/9). Only use infusion stands or poles that are sufficiently stable.

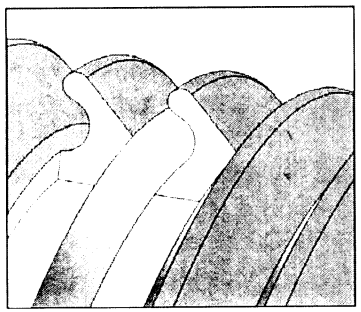
Connect power cable to power supply. Before connecting to mains power supply, check the voltage specified on the device label. The device gives a short beep and the standby light (Diag.1/5) lights up.

If a different temperature to 38.5°C is desired, it can be preset in Standby mode using the controls △ and ▽ (Diag.1/6 and Diag.1/7). If an adjustment control is pressed, the visual display indicates the existing preset temperature. By repeated operation of the control △ or ▽ the temperature can be reset. The indicator automatically goes out after approximately 7 seconds. Resetting of temperature can only be performed in Standby mode.

Heating of the BW 585 can be started by pressing the control ⏻ (Diag.1/3). The BW 585 attains the set target temperature within 1 minute. The indicator display shows the actual temperature (+/- 0.5°C) as an illuminated band.

Select suitable consumable material. See section „consumable material".

Prepare infusion or transfusion. Attention: The length of the tube between the BW 585 and the patient must be at least 40 cm and the tube must not be streched.



Diag. 2
Position of the tube in the groove of the heat exchanger

Beginning at the back of the heat exchanger the extension tube is gently pulled and coiled in an anti-clockwise direction towards the front. It is advisable that the gap between the BW 585 and patient does not exceed much more than 80 cm.

Important: The tube must be completely inserted into the groove (Diag. 2). The flow direction specified in diagram 1 must be complied with.

3.2 ALARMS

The BW 585 can trigger two types of temperature alarm:

The low temperature alarm is activated when the temperature of the heat exchanger drops below 36.5°C. The audio low temperature alarm is deactivated during the first 60 seconds after switching on.

The high temperature alarm is activated when the temperature of the heat exchanger exceeds 42.0°C. In this event visual and audio alarm signals are given and the heating is switched off. To reset the device or switch off the alarm, the device must first be disconnected from the power supply.

Attention: The temperature alarm can also be set off externally e.g. by exposure to sunlight.

3.3 SHUTTING DOWN THE DEVICE

After being used for treatment, the device is shut down as follows:

Switch the device into Standby mode using control ⏻ (Diag.1/3).

Release pressure from the system by switching off any pressure cuffs or infusion pumps used. Empty and disconnect the system as far as possible.

Remove the consumable material from the heat exchanger (Diag.1/1) and dispose of it according to the relevant regulations.

Disconnect the device from the power supply and clean and sterilize as in section „cleaning and disinfection" of these instructions.

4 MAINTAINANCE

The BW 585 is designed as a low-maintenance device. To preserve the quality and functional safety, please comply with the following points:

- Always keep the device and its accessories clean (see section: cleaning and disinfection).
- The periodic technical safety inspections must be carried out (see section: periodic inspections)

5 CLEANING AND DISINFECTION

The device may only be cleaned using a soft cloth with water-soluble, non-aggressive cleaning agent or a special cleaning agent for plastics.

For the purposes of disinfection, ready-made alcohol-based spray disinfectants can be used.

Important: Before cleaning or disinfection, the device must always be disconnected from the mains power supply.

6 PERIODIC INSPECTIONS

Periodic technical safety inspections must be performed on the BW 585 at least every 12 months by persons who on the basis of their training, knowledge and practical experience are qualified to carry out such technical safety testing.

The results of the periodic inspection are to be entered, together with the date and the inspecting agency, on the reverse side of the instructions for use.

Important: If a malfunction is identified in the periodic inspection, affix a suitable warning notice on the device to ensure that it can no longer be used until the necessary repairs have been carried out.

CHECKING THE WARM-UP PERIOD

This is the time taken by the BW 585 to heat up to 38.5°C from room temperature. The device is malfunctioning if it takes much longer than one minute.

CHECKING THE CONTROL TEMPERATURE

The control temperature is checked on the groove bed of the heat exchanger. The sensor of a suitable contact thermometer (tolerance +/- 0.15°C) is fixed to this place e.g. using a piece of infusion tubing. The check is performed at a temperature setting of 38.5°C. The measured value is read after it has stabilized. The difference must not exceed +/- 0.5°C. There is a malfunction if a difference from control temperature of greater than +/- 0.5°C is obtained.

CHECKING THE LOW TEMPERATURE ALARM

Preheat the device to 38.5°C, then disconnect the mains plug. Hold down the control ▽ and reconnect the mains plug. Push the ⏻ switch. The device is now in an operational state where all the alarms are active, but the heating is switched off. The BW 585 now slowly cools down. When the temperature drops below the 36.5°C threshold, the low temperature alarm should be active.
For reasons of safety, short beeping sounds are given at intervals of a second in this operational mode and the LED ON and STANDBY indicators flash alternately (Diag.1/4 and Diag.1/5). There is a malfunction if the low temperature alarm is not triggered.

CHECKING THE HIGH TEMPERATURE ALARM

Preheat the device to 41°C and wait for the temperature to stabilize, then disconnect the mains plug. Hold down the control △ and reconnect the mains power plug. Push the ⏻ switch. The device now heats up to a target temperature of 42.5°C. Observe the temperature indicator carefully. The high temperature alarm should be triggered at a temperature of 42°C.
For reasons of safety, short beeping sounds are given at intervals of a second in this operational mode and the LED ON and STANDBY indicators flash alternately (Diag.1/4 and Diag.1/5). There is a malfunction if the high temperature alarm is not triggered.

VISUAL CHECK OF GENERAL CONDITION AND STICKERS

The device should be checked for mechanical damage (general condition) and for the completeness of sticker information, particularly the plate on the reverse. There is a malfunction if mechanical damage to the device is evident which could be harmful or impair the functional operation of the device.

ELECTRICAL SAFETY

All relevant electrical safety data should be checked, particularly the earth conductor resistance (< 0.3 Ohm) and leakage current (< 0.75 mA). There is a malfunction if there is a value outside the tolerances.

7 MANUFACTURER LIABILITY

The manufacturer and the supplier of the device reject all liability if:

- the device is not used in accordance with the instructions for use
- the operating personnel are inadequately qualified or are not sufficiently informed about the functioning of the device on the basis of the instructions for use and the safety instructions
- repairs are not performed exclusively by the manufacturer or by persons and service centres expressly authorised by manufacturer
- the device is used in places in which the electrical installations do not comply with the applicable national standards, or if power supply during the period of use of the device is not guaranteed
- original spare parts material are not used or the maintenance interval is not complied with.

Disposal of the device and its accessories is carried out in accordance with the applicable local regulations.

8 WARRANTY CONDITIONS

The manufacturer guarantees that all flaws of material and workmanship which arise within 24 months from date of purchase will be repaired free of charge. Claims are only accepted under the following terms:

- The manufacturer and/or supplier is informed immediately of the fault for which the warranty claim is being made.
- The instructions of the manufacturer and/or supplier on storage or return of the device are complied with.
- Presentation of a legible copy of the invoice for the device concerned, showing the date of purchase.
- An exact description of the defects or malfunctions identified by the customer.

The manufacturer's warranty will be void if it is found that the maintenance, disinfection and inspection instructions have not been followed according to the instructions for use, the device was damaged by force or operating error, or was used in any way contrary to the instructions for use and safety instructions. The warranty will also be void if not original Biegler materials were used as replacement parts, or measures for repair were undertaken by persons not authorised by the manufacturer or supplier.

If the manufacturer is required to meet a warranty claim in accordance with these terms, the customer shall bear the costs and risks of transport of the device from and to the place of use.

The manufacturer and/or supplier under no circumstances assume liability for slight negligence. The compensation for lost earnings and profits is likewise excluded.

9 RETURN OF DEVICES

Devices must be carefully cleaned and disinfected before being placed in the original packaging for returning.

If the original packaging is no longer available, the product has to be suitably packaged for the method of dispatch.

10 MANUFACTURER`S DECLARATION

The blood and infusion warmer BW 585 is a medical product as defined by Directive 93/42/EEC.

This is documented with the CE mark.

Notified Body: TÜV Product-Service, Approval Number CE0123

11 ELECTROMAGNETIC EMISSION

Table 201 – Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS (see 6.8.3.201 a) 3))

The BW 585 is intended for use in the electromagnetic environment specified below. The customer or the user of the BW 585 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The BW 585 uses RF energy only for its internal function. Therefor, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The BW 585 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Table 202 – Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS (see 6.8.3.201 a) 6))

Guidance and manufacturer´s declaration – electromagnetic immunity

The BW 585 is intended for use in the electromagnetic environment specified below. The customer or the user of the BW 585 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	< 5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles < 5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BW 585 requires continued operation during power mains interruptions, it is recommended that the BW 585 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE U_T is the a. c. mains voltage prior to application of the test level.

Table 204 – Guidance and manufacturer's declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Guidance and manufacturer's declaration – electromagnetic immunity

The BW 585 is intended for use in the electromagnetic environment specified below. The customer or the user of the BW 585 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the BW 585, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			11.1.1 Recommended separation distance
Conducted RF IEC 61000-4-6	3 V 150 kHz to 80 Mhz		$d = 1{,}17\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz		$d = 0{,}35\sqrt{P}$ 80 MHz to 800 Mhz $d = 0{,}7\sqrt{P}$ 800 MHz to 2,5 GHz
			where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b]
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]
			Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BW 585 is used exceeds the applicable RF compliance level above, the BW 585 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the BW 585.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 206 – Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING (see 6.8.3.201 b))

Recommended separation distances between

portable and mobile RF communications equipment and the BW 585

The BW 585 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BW 585 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BW 585 as recommended below, according to the maximum output power of the communications equipment.

	11.1.1.1 Separation distance according to frequency of transmitter		
	m		
Rated maximum output of transmitter W	150 kHz to 80 MHz $d = 1{,}17\sqrt{P}$	80 MHz to 800 MHz $d = 0{,}35\sqrt{P}$	800 MHz to 2,5 GHz $d = 0{,}7\sqrt{P}$
0,01	0,12	0,04	0,07
0,1	0,37	0,11	0,22
1	1,17	0,35	0,70
10	3,69	1,11	2,21
100	11,67	3,50	7,00

For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12 SYMBOLS

Certifies compliance with 93/42/EEC


Observe the instructions for use


Do not dispose of this product as unsorted municipal waste


Control for increasing the temperature setting


Control for decreasing the temperature setting


Control for switching On / Standby

13 OPERATING AND STORAGE CONDITIONS

Permissible environmental conditions for transport and storage:

Temperature:	10 – 40°C
Relative humidity:	30 – 75 %
Air pressure:	700 – 1060 hPa

The operating temperature must be in the range of: 10 – 30 °C

Values higher or lower than the ranges specified above may cause damage to the device or its accessories.

14 TECHNICAL DATA

Device:	Blood and infusion warmer
Type designation:	BW 585
Voltage:	230 V / 50-60 Hz or 110 V / 50 Hz check the voltage specified on the device label
Power consumption:	280 W
Type of protection against electric shock:	I
Degree of protection against electric shock:	B
Degree of protection against ingress of liquids:	IPX4
Safety protection:	230V: primary 2 x 1.6 AT secondary 315 mAT 110V: primary 2 x 3.15 AT secondary 315 mAT
Temperature setting:	37°C - 41°C adjustable in steps of 0.5°C
High temperature cut-out:	42°C / 42.5°C / 45°C±3°C
Max. system pressure:	300 mmHg
Dimensions:	WxHxD 140 x 190 x 240 mm
Weight:	2.5 kg
Classification:	IIb according to rule 9
Type of operation:	continuous operation

15 MANUFACTURER

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